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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,544	12/14/2005	Breda Mary Cullen	JJM5011USPCT	6443
27777 7590 10/01/2007 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER WESTERBERG, NISSA M	
			ART UNIT 1609	PAPER NUMBER
			MAIL DATE 10/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/560,544		CULLEN ET AL.	
	Examiner		Art Unit	
	Nissa M. Westerberg		1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 - 13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3 sheets</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of Claims

Claims 1 – 13 are pending and are currently under examination.

Claim Rejections - 35 USC § 112 2nd Paragraph

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "at least about" is indefinite. "At least" means a minima whereas "about" indicates a range centered on the value. Therefore, what values are included in "at least about" is unclear and the metes and bounds of the claims cannot be determined.

3. Claim 13 recites the limitation "the material has a free radical activity in the diphenylpicrylhydrazyl (DPPH) test for antioxidant activity as herein defined" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim. The claims should be able to stand alone and importation of limitations from the specification should not be required to determine the metes and bounds of the claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1 – 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al. (EP 0 368 253).

Partain et al. teaches delivery systems comprising aminopolysaccharides such as chitosan derivatives (col 2, ln 32 – 35) and glycosaminoglycans such as hyaluronic acid, chondroitin sulfate and heparin (col 8, ln 55 – 59). Compositions comprising chitin and chitosan are useful in accelerating the healing rate of wounds (col 8, ln 35 – 38). Additionally, this delivery system can contain antiseptic agents such as acridine dyes (col 10, ln 12). The compositions can be applied to the skin as a pre-formed film or sponge (col 4, ln 1 – 4). The compositions of Partain et al. are not explicitly disclosed as being bioabsorbable. However, the dissolution is a property of the polysaccharide used and since the polysaccharides taught are the same, the delivery systems of Partain et al. are bioabsorbable.

Therefore it would have obvious to one of ordinary skill at the time of the instant invention with a reasonable expectation of success to prepare a composition comprising a bioabsorbable aminopolysaccharide with an antioxidant dyestuff.

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6. Claims 7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al. as applied to claims 1 – 6 above in view of Fowler et al. (US Patent 5,667,501).

As discussed above, Partain et al. teaches aminopolysaccharide compositions comprising acridine dyes. Partain et al. does not teach the amount of dye present or the free radical activity of the polymer.

Fowler et al. teaches wound dressing that contain chemically modified polymers. The base polymer does not possess the free radical activity but groups with the desired activity are added to the base polymer (col 2, ln 45 – 50). The free radical activity of the polymers in the DPPH test can be in the range of about 15 – 80% (col 2, ln 24 – 25).

Acridine dyes can be oxidized and therefore act as an antioxidant. Given the effective range of free radical activity taught by Fowler et al., it would have been to obvious to one of ordinary skill in the art to add the antioxidant dyestuff at a level that resulted in an free radical activity in the effective range with a reasonable expectation of success.

7. Claims 8 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al. and Fowler et al. as applied to claims 1 – 7 and 13 above in further view of Nimrod et al. (WO 87/05517).

As discussed above, Partain et al. teaches delivery systems comprising aminopolysaccharides such as chitosan derivatives (col 2, ln 32 – 35) and

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glycosaminoglycans such as hyaluronic acid, chondroitin sulfate and heparin (col 8, ln 55 – 59). In addition to antiseptic agents such as acridine dyes (col 10, ln 12), this delivery system can also contain antibiotics (col 9, ln 55). Fowler et al. teaches the desired free radical activity and therefore the amount of antioxidant present in the wound dressing.

Nimrod et al. teaches heavy metal salts of hyaluronic acid, an anionic polymer where the heavy metal can be silver (p 4, ln 27). Silver ions are effective antimicrobial agents without significant side effects that are rarely associated with silver antibiotic-resistant strains of bacteria. Silver salts are useful as topical anti-infectives or antiseptics (p 3, ln 7 – 13).

Given the teachings of Partain et al. and Nimrod et al., it would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a composition comprising both a heavy metal salt of the polysaccharide and the acridine dye with a reasonable expectation of success given that both disclose wound dressing materials.

8. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al. and Fowler et al. as applied to claims 1 – 7 and 13 above in further view of Gibbins (US Patent 6,355,858 B1).

As discussed above, Partain et al. and Fowler et al. teaches aminopolysaccharide compositions comprising acridine dyes. Partain et al. does not

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teach that the delivery vehicle is in the form a sheet or that the material is sterile and placed in a microorganism-impermeable container.

Gibbins teaches wound dressings that administer an active agent (col 4, ln 8 – 11). Active agents can include silver salts as an anti-microbial agent (col 7, ln 2). The matrix material can be cut from a sheet and sterilized by a number of methods (col 12, ln 52 – 65).

It would have been obvious to one of ordinary skill in the art with a reasonable expectation of success to take the wound dressing composition of Partain et al. and Fowler et al., form it into a sheet, cut to the desired pattern or shape, and then sterilize the wound dressing material as taught by Gibbins. Once sterile, it would be obvious to place the sterile material in a container or packaging to maintain the sterility of the matrix (“microorganism-impermeable container”).

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

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by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1 – 3 and 12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4 and 13 of copending Application No. 11/608,553 in view of Partain et al. The claims of '553 recite wound dressings comprising a human recombinant collagen and an oxidized cellulose. The claims of the instant application recite a wound dressing material, which may be made of mixtures of collagen and oxidized cellulose with an antioxidant dyestuff. Partain et al. teaches aminopolysaccharide delivery systems (col 2, ln 32 – 35) comprising

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acridine dyes as antiseptic agents (col 10, ln 12). Given that the compositions of Partain et al. can be used to dress wounds (col 8, ln 35 – 38), it would have been obvious to one of ordinary skill to add a dyestuff such as acridine with antioxidant properties to the compositions of '553 to arrive at the claims of the instant application.

This is a provisional obviousness-type double patenting rejection.

11. Claims 8 – 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 13 of copending Application No. 10/579,850 in view of Partain et al. The claims of '850 recite wound dressing materials comprising a polymeric substrate such as collagen, oxidized cellulose and other bioabsorbable materials with a silver salt and a dyestuff to stabilize the silver salt. That dyestuff may be antioxidant dyes such as aniline or acridine dyes (claims 8 and 9). Claims 8 – 10 of the instant application recite wound dressing materials comprising a solid bioabsorbable substrate with an antioxidant dyestuff, present in amounts ranging from about 0.2 to about 2% by dry weight, further comprising a silver salt. The specific disclosure of the claims of the instant application make obvious the generic claims in '850.

This is a provisional obviousness-type double patenting rejection.

12. Claims 8 – 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 11 of copending Application No. 10/527,421 in view of Partain et al. The claims of '421 recite

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wound dressing materials comprising complexes of anionic polymer with silver wherein the anionic polymer can anionic polysaccharides such as oxidized cellulose and other cellulose derivatives. Partain et al. teaches aminopolysaccharide delivery systems (col 2, ln 32 – 35) comprising acridine dyes as antiseptic agents (col 10, ln 12). Given that the compositions of Partain et al. can be used to dress wounds (col 8, ln 35 – 38), it would have been obvious to one of ordinary skill to add a dyestuff such as acridine with antioxidant properties to the compositions of '421 to arrive at the claims of the instant application.

This is a provisional obviousness-type double patenting rejection.

13. Claims 1 – 3 and 12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5 – 8 and 10 – 13 of copending Application No. 10/528,262 in view of Partain et al. The claims of '262 recite a wound dressing composition comprising chitosan and oxidized cellulose. These are two bioabsorbable polymers that are bioabsorbable substrates in the instant application. Partain et al. teaches aminopolysaccharide delivery systems (col 2, ln 32 – 35) comprising acridine dyes as antiseptic agents (col 10, ln 12). Given that the compositions of Partain et al. can be used to dress wounds (col 8, ln 35 – 38), it would have been obvious to one of ordinary skill to add a dyestuff such as acridine with antioxidant properties to the compositions of '262 to arrive at the claims of the instant application.

This is a provisional obviousness-type double patenting rejection.

Conclusion

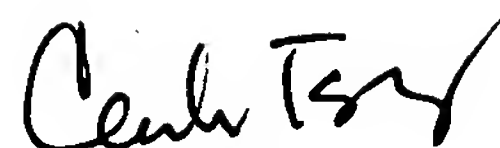
Claims 1 – 13 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571) 270-3532. The examiner can normally be reached on M - F, 7:30 a.m. - 5 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718 or Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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